X. July 21, 2014, Letter to Demson Fuller from The Acta Group, *EPA AD and Industrie De Nora July 9, 2014, Meeting and Follow-Up*, and cover e-mail

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July 21, 2014

Via E-Mail

Mr. Demson Fuller
U.S. Environmental Protection Agency
Office of Pesticide Programs (MC 7510P)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Re: EPA AD and Industrie De Nora July 9, 2014, Meeting and Follow-Up

Dear Demson:

On behalf of Industrie De Nora S.p.A. (De Nora), The Acta Group (Acta®) thanks you for the July 9, 2014, meeting. We found the information exchange helpful and hope that the U.S. Environmental Protection Agency (EPA) Antimicrobials Division (AD) did as well. We summarize below the main discussion points from the meeting, including the two issues that required further discussion within AD, which appear in bold face. We look forward to your response on these issues. We have attached the draft proposed label in connection with this follow-up.

- Certificates of analysis provided by the supplier of the pharmaceutical grade sodium chloride for five separate batches, along with an explanation of why these analyses are sufficient for AD's purposes, will suffice to meet the preliminary analysis requirement.

- EPA has requested analyses of the 0.6% and 0.1% solutions generated by five separate Giselle machines for confirmation of the sodium hypochlorite concentrations; additional analyses similar to those conducted for a preliminary analysis, such as for impurities, are not required.

- For the analyses of the 0.6% and 0.1% solutions, commercial reagents and test standards were used that were supplied according to commercial specifications. Accordingly, these standards were not separately validated. **We expect this is acceptable but AD has agreed to discuss and respond.**

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- As the efficacy studies contain sodium hypochlorite concentration data for the periods for which the product will be claimed as efficacious (24 and 48 hours), De Nora will cite these studies to support the storage stability statements. De Nora also will cite EPA's database to address the storage stability of sodium chloride.

- The 0.6% disinfectant and 0.1% sanitizer bottles will be different colors and labeled with appropriate use directions. A printer integrated with the Giselle equipment will print out the date and time of batch production, so the user knows by when the solution must be used. **AD agreed to review the draft labeling, including the bottle labeling, and consider whether a master label-type format or another approach should be used.** AD stated the Giselle user manual also must be submitted.

- AD reiterated its prior inquiry about the effects of hard water on product efficacy and asked De Nora to submit data to address this issue. De Nora reports water hardness in European units and will comply with AD's request to convert those units into parts per million (ppm) equivalents as calcium carbonate.

- In response to AD's inquiry about quality control for the Giselle machine, De Nora stated that for each batch, internal monitoring controls the production process parameters for voltage, current, and electrolysis time to confirm the selected sodium hypochlorite concentration is correct. During product development, De Nora conducted extensive lifecycle testing on the Giselle machines to confirm consistent and reliable batch production over the life of the machine. Additionally, Giselle is programmed to require cleaning every 80 production cycles and calibration every 100 cycles.

- AD agreed to review and consider the Experimental Use Permit (EUP) exemption request upon submission and respond timely.

De Nora appreciates AD's ongoing assistance and looks forward to AD's response. As always, please call if you have any questions.

Sincerely,

Sheryl L. Dolan

Attachment
cc: Mr. Lance Wormell (w/attachment) (via e-mail)
Mr. Mark Perry (w/attachment) (via e-mail)

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